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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,857	12/29/2000	Ron J. Doyle	12818.1USU1	8938

23552 7590 06/18/2003

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/18/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/750,857

Applicant(s)

DOYLE ET AL.

Examiner

Khatol S Shahn-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13-21,51-54 and 57 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-11,13-18, 51-54 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3-11,13-21,51-54 and 57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicants' amendments and response received April 02, 2003, paper 16 is acknowledged. Claims 2, 12, 55 and 56 were canceled. Claims 1, 9, 15 and 52 were amended. Specification pages 1 and 15 were amended.
2. Currently claims 1, 3-11, 13-21, 51-54 and 57 are pending.
3. Claims 1, 3, 4, 8-11, 13-18, 51-54 and 57 are under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or 1449 have been submitted with this office action.

Objections Withdrawn

6. Objection to the priority statement, made in paragraph 6 of the office action mailed 12/2/2002, paper #14 is withdrawn in view of applicants' amendments.
7. Objection to the specification, made in paragraph 7 of the office action mailed 12/2/2002, paper #14 is withdrawn in view of applicants' amendments.

Rejections Moot

8. Rejections of claims 2, 12, 55 and 56 under 35 U.S.C. 112 second paragraph, made in paragraph 6 of the office action mailed 12/2/2002, paper #14 is moot in view of

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applicants' cancellation of the claims.

9. Rejection of claim 55 under 35 U.S.C. 102 (b), made in paragraph 9 of the office action mailed 12/2/2002, paper #14 is moot in view of applicants' cancellation of the claim.
10. Rejection of claims 12 and 56 under 35 U.S.C. 103 (a), made in paragraph 11 of the office action mailed 12/2/2002, paper #14 is moot in view of applicants' cancellation of the claims.
11. Rejections of claims 1, 3, 4, 8-11, 13-18, 51-54 and 57 under 35 U.S.C. 112 second paragraph, made in paragraph 6 of the office action mailed 12/2/2002, paper #14 is withdrawn in view of applicants' amendments.
12. Rejections of claims 1, 3, 51, 53 and 54 under 35 U.S.C. 102 (b), made in paragraph 9 of the office action mailed 12/2/2002, paper #14 is withdrawn in view of applicants' amendments.
13. Rejections of claims 9, 10 and 17 under 35 U.S.C. 102 (b), made in paragraph 10 of the office action mailed 12/2/2002, paper #14 is withdrawn in view of applicants' amendments.
14. Rejection of claims 9-11, 13-15, 17-18 and 57 under 35 U.S.C. 103 (a), made in paragraph 11 of the office action mailed 12/2/2002, paper #14 is withdrawn in view of applicants' amendments.

Objections Maintained

15. Objection to the specification, made in paragraph 7 of the office action mailed 12/2/2002, paper #14 in regard to the trademarks in the specification is maintained. Applicants' amendments and response received April 02, 2003 did not address this issue.

New Grounds for Rejections

Claim Rejections - 35 USC § 112

16. Claims 15 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 15 recites the limitation "the method of claim 1, wherein a lectin comprises **the** carbohydrate-binding site". There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite a carbohydrate-binding site.

Amended claim 52 is still not clear and confusing. There is an extra (a) before "at least one member" in line 2. It is not clear what applicants' intend in reciting "and man-made device that is placed in the catheter, implant, prosthesis or man-made device being located in or on a mammal's body or body cavity". What is this man-made device? Do the applicants consider catheter, implant, or a prosthesis man-made devices?

Claim Rejections - 35 USC § 103

17. Claims 1, 3, 4, 8-11, 13-18, 51-54 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen (WO 98/26807) in view of Echigo, Takashi (WO 97/28257) and further in view of Singh et al. (Carbohydrate Research Vol. 244, PP. 137-147, 1993). Applicants' IDS already made of record.

Claims specially as recited in the amended independent claims 1 and 9 are drawn to a method of reducing binding or adhesion in a microorganism, respectively comprising contacting or exposing the microorganism to an enzyme (i.e. polyphenol oxidase) which reduces adhesion by a microorganism.

Johansen teaches a method of reducing binding or adhesion by a microorganism comprising contacting or exposing the microorganism to an effective amount of an enzyme which reduces adhesion by a microorganism. (see page 1 and claim 1). Johansen teaches that bacteria have a marked tendency to adhere to a surface and initiate the formation of biofilms (page 1, lines 9-10). Johansen also teaches that a variety of enzymes reduce adhesion of these bacteria from the surface (see page 2, lines 10-14 and page 4). Johansen teaches microorganisms comprising prokaryotes, gram-negative bacteria and *E.coli* (see page 3, lines 31-36 and claim 10). Johansen teaches that this removal or release (reducing adhesion) of biofilm from the surface takes place by catalytic action of the enzyme. (see page 3, lines 1-2, page 22 (results) and table 1, page 24). Johansen teaches wherein the surface comprises medical devices and implants. (see page 1, lines 10-30, page 2-3 and page 31, lines 5-25). Johansen teaches variety of enzymes including oxidase and peroxidase (see abstract, pages 4-5). Johansen does not explicitly teach polyphenol oxidase. However, Echigo teach a method of contacting an organism with polyphenol oxidase for the purpose of inactivating the microorganism (i.e. reducing the binding of microorganism to a surface) see page 2, lines 29-32, page 15, lines 21-34 and claim 11.

Echigo does not teach modification of a side chain of an amino acid. However, Singh et al. teach modification of a side chain of an amino acid. (see abstract and materials and methods). Singh et al. teach that the active site of glucan- binding lectin of *Streptococcus sorbinus* was probed by specific amino acid modifying reagents. Singh et al. teach chemical modification of lectins, including lectin adhesins (see page 138). Singh et al. teach essential amino acid residue such as tyrosine needed for adherence (see abstract). Singh et al. also teach chemical modification of *E. coli* adhesins (see page 146).

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It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the methods taught by Johansen with the methods taught by Echigo and Singh et al. to obtain the claimed invention.

One having ordinary skill in the art would have been motivated by the teachings of Singh et al. of the essential role of bacterial lectin adhesins in the pathogenesis and growth of bacteria (see pages 137-138 and 146) and by the teachings of Johansen that enzymes specially oxidoreductase enzymes such as oxidase reduce the tendency of bacteria to adhere to surfaces and prevent biofilms (see abstract, page 1, and page 3) to develop a method of reducing adhesion by a microorganism comprising exposing the microorganism to an effective amount of an enzyme (polyphenol oxidase) which reduces adhesion by a microorganism.

Conclusion

18. Claims 1, 3, 4, 8-11, 13-18, 51-54 and 57 stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

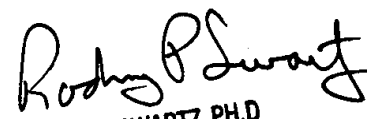


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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June 11, 2003



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER